

Docket No: 22740-1

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Geza Bruckner et al

Serial No.: 10/042,990 : Group Art Unit: 1617

Filed: January 9, 2002 : Examiner: E. J. Webman

For: Dietary Compositions :

Box AF
Commissioner for Patents
Washington, DC 20231

Dear Sir:

Transmitted herewith is a Request for Reconsideration under 37 C.F.R. 1.116 in the above-identified application.

[] additional fee is required.

[X] also attached: References (3) - McCarthy et al; Picard et al; and Hernandez-Ono et al.

The fee has been calculated as shown below:

	NO. OF CLAIMS	HIGHEST PREVIOUS PAID FOR	EXTRA CLAIMS	RATE	FEE
Total Claims	24	24	0	x \$18 =	\$---
Independent Claims	2	3	0	x 84 =	\$---
TOTAL FEE DUE					---

[x] The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment, to Deposit Account No. 04-1133, including any filing fees under 37 CFR 1.16 for presentation of extra claims and any patent application processing fees under 37 CFR 1.17.

Respectfully submitted,

By:

Rebecca Brown
Rebecca A. Brown
Registration No. 47,452
DINSMORE & SHOHL LLP
1900 Chemed Center
255 East Fifth Street
Cincinnati, Ohio 45202
(513) 977-8679

Date: February 12, 2003
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Docket No: 22740-1A

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Applicant: Geza Bruckner et al. : Paper No:
Serial No.: 10/042,990 : Group Art Unit: 1617
Filed: January 9, 2002 : Examiner: E. J. Webman
For: **DIETARY COMPOSITIONS**

Box AF
Commissioner for Patents
Washington, DC 20231

REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. 1.116

Dear Sir:

In response to the Official Action dated November 12, 2002, Applicants respectfully request reconsideration of the patentability of claims 3-4, 6-8, 29-30 and 35-37.

REMARKS

The Official Action dated November 12, 2002 has been carefully considered. It is believed that the remarks set forth herein demonstrate the patentability of claims 3-4, 6-8, 29-30 and 35-37 and therefore place the present application in condition for allowance. Reconsideration is respectfully requested.

Claims 3-4, 6-8, 29-30 and 35-37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jackson et al (WO 98/04248) in view of Fort (DE 29805782 U1). The Examiner asserted that Jackson et al teach a dietary supplement composition for post-menopausal women containing 1-50 mg phytoestrogen, and asserted that Jackson et al

specify genistin. The Examiner further asserted that the Jackson et al composition may be formulated with cereal. The Examiner acknowledged, however, that Jackson et al do not teach compositions incorporating carnitine. The Examiner therefore relied upon the Fort reference, asserting that Fort teaches a dietary cereal containing carnitine. The Examiner further asserted that it would have been obvious to one of ordinary skill in the art to add carnitine to the composition of Jackson et al to achieve the beneficial effects of supplementing the dietary needs for post-menopausal women. The Examiner asserts that the primary reference teaches lessening the risk of heart disease and the secondary reference teaches conversion of body fat into energy. The Examiner asserts that it is well known that body fat is a risk factor in heart disease. Thus, the Examiner asserts that it would be obvious to add an agent that promotes loss of body fat to improve a composition for reducing the risk of heart disease.

However, as will be set forth in detail below, it is believed that the dietary compositions defined by claims 3-4, 6-8, 29-30, and 35-37 are non-obvious over Jackson et al in view of Fort. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

According to claim 29 of the present application, dietary compositions comprise a mammal food base, a component comprising phytoestrogen, phytoandrogen or a mixture thereof in an amount sufficient to reduce weight gain normally incurred in the mammal type subsequent to neutering, castration, spaying, ovariectomy or ovariohysterectomy or post menopause, when the dietary composition is administered to a mammal on a regular basis. These dietary compositions further comprise at least one component selected from the group consisting of carnitine, inulin, conjugated linoleic acid and fructose oligosaccharide.

Fat accumulation, which is reduced by the compositions of the patent invention, has a distinctly different pathway and is regulated by different signaling molecules as compared with fat mobilization and subsequent oxidation. Compositions as described in claim 29, comprising phytoestrogen, phytoandrogen, or a mixture thereof and at least one component selected from the group consisting of carnitine, inulin, conjugated linoleic acid and fructose oligosaccharide, are targeted at decreasing lipoprotein lipase (LPL) activity in both types of adipose tissue but with a targeted effect on visceral fat (see, for example, McCarty, M. F., Modulation of adipocyte lipoprotein lipase expression as a strategy for preventing obesity, *Med. Hypothesis* 2001, 57:192-200). Upon administration of the present compositions, decreased visceral and subcutaneous adipose tissue are formed due to the decreased LPL. As a result, there is decreased weight gain and the fatty acids which are not stored will be more efficiently used, such as by oxidation, by the addition of carnitine, inulin, conjugated linoleic acid or fructose oligosaccharide to the diet. The deposition of fat is dependant on insulin activity which is diminished by estrogenic compounds and their antagonists (see, for example, Picard, E. et al., Effects of the estrogen antagonist EM-652.HCl on energy balance and lipid metabolism in ovariectomized rats, *Int J Obes Relat Metab Disord.* 2000, 24(7):830-40).

On the other hand, mobilization of fat stores and subsequent oxidation of these fatty acids, as in dieting, utilize different hormonal signaling (hormone sensitive lipase). The combinations of phytoestrogen, phytoandrogen, or mixture thereof and at least one component selected from the group consisting of carnitine, inulin, conjugated linoleic acid and fructose oligosaccharide are unique combinations to prevent fat deposition and thereby decrease body weight and body fat gains in humans and non human mammals.

Jackson et al disclose dietary supplements that supply a variety of nutrients to supplement the dietary needs of women in order to prevent or reduce life-stage associated health risks during each principle adult life stage (page 8, lines 6-16). The Jackson et al compositions comprise specified amounts of calcium, magnesium, boron, copper, manganese, zinc, iron, folic acid, chromium, vitamin D, B₁₂, B₆, E, and C, and phytoestrogen in a biologically acceptable carrier. Applicants find nothing in Jackson et al to suggest that modification of the disclosed compositions could be useful to either improve the Jackson et al dietary supplement or to prevent weight gain in mammals subsequent to neutering, castration, spaying, ovariectomy or ovariohysterectomy, or post menopause, as provided by compositions of the present invention.

The Examiner has acknowledged that Jackson et al do not teach compositions incorporating carnitine. Similarly, Jackson et al fail to teach or suggest compositions comprising inulin, conjugated linoleic acid or fructose oligosaccharide. The Examiner purports to overcome the deficiencies of Jackson et al with the Fort reference. However, Applicants submit that these references are not properly combinable. Fort discloses a dietary food supplement that, due to the presence of L-carnitin and lecithin, helps to convert body fat into energy and to increase the useful conversion of sugar. Fort further discloses that L-carnitine contributes to a reduction in subcutaneous fat, implying fat mobilization pathways are being effected and not fat deposition pathways.

Fort is not properly combinable with Jackson et al, however, as one skilled in the art would recognize significant differences between the Jackson et al nutritional dietary supplements that are designed to address common health risks and the Fort dietary supplements that are designed to provide energy. Moreover, no motivation would have existed for one skilled in the art to look to energy providing dietary supplements as taught by

Fort to improve the women's dietary supplement of Jackson et al. The Examiner asserts that it is well known that body fat is a risk factor in heart disease, and, therefore, that it would be obvious to add an agent that promotes loss of body fat to improve a composition for reducing the risk of heart disease. However, in assessing risk of heart disease, Applicants submit that one skilled in the art will recognize that the type of body fat is a more important risk factor than overall adiposity. That is, visceral fat has been well correlated with increased risk, while subcutaneous fat with which Fort is concerned (gluteofemoral fat) has little predictive value in assessing heart disease (see, for example, Hernandez-Ono, A. et al., Association of visceral fat with coronary risk factors in a population-based sample of postmenopausal women, *Int J Obes Relat Metab Disord.* 2002 26(1):33-9) (Reference enclosed.). Therefore, one skilled in the art would not look to carnitine, as an agent to promote the reduction of subcutaneous fat, which is not associated with a risk of heart disease, to improve a dietary composition for reducing the risk of heart disease.

The Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select elements from the cited prior art references for combination in the manner claimed, *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). The Examiner cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention; rather, the Examiner has the burden to show some teaching or suggestion in the references to support their use in a particular claimed combination, *Smith-Kline Diagnositcs, Inc. v. Helena Laboratories Corp.*, 8 U.S.P.Q.2d 1468, 1475 (Fed. Cir. 1988). Applicants respectfully submit that this burden has not been met as Forts' concern with subcutaneous fat is not relevant to Jackson et al's dietary compositions for reducing risk of heart disease.

The mere fact that the prior art could be modified would have not made the modification obvious unless the prior art suggested the desirability of the modification, *In re Mills, supra*; *In re Fritch*, 23 U.S.P.Q. 2d 1780 (Fed. Cir. 1992). In order for a combination of references to render an invention obvious, a combination of the teachings of all or any of the references must suggest, expressly or by implication, the possibility of achieving further improvement by combining such teachings along the lines of the invention, *In re Sernaker*, 217 U.S.P.Q. 1, 5 (Fed. Cir. 1983). Applicants find no suggestion, express or implied, relating to the possibility of achieving further improvement in the Jackson et al composition by combining the teachings of Fort along the lines of the present invention. Furthermore, Applicants find no suggestion or desirability for forming a composition as claimed comprising a phytoestrogen, phytoandrogen, or mixture thereof in combination with at least one component selected from the group consisting of carnitine, inulin, conjugated linoleic acid and fructose oligosaccharide.

It is therefore submitted that the dietary compositions defined by claims 3-4, 6-8, 29-30 and 35-37 are non-obvious over the Jackson et al reference in view of Fort, whereby the rejection under 35 U.S.C. §103 has been overcome. Reconsideration is respectfully requested.

Respectfully submitted,


Rebecca A. Brown, Reg. No. 47,452
Attorney for Applicants
Dinsmore & Shohl LLP
1900 Chemed Center
255 East Fifth Street
Cincinnati, OH 45202
(513) 977-8679
(513) 977-8141 Facsimile

869635